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In re the Application of

Louis V. Kirchhoff

Group Art Unit: 1645

Serial No.: 10/726,692

Examiner: P. Baskar

Filed: December 4, 2003

For: **RECOMBINANT POLYPEPTIDES FOR DIAGNOSING INFECTION WITH
TRYPANOSOMA CRUZI**

PRELIMINARY AMENDMENT IN RESPONSE TO TELEPHONE RESTRICTION

Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

In response to the telephone restriction requirement and prior to examination on the merits,
please amend the above-identified application as follows:

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1. (Withdrawn) A recombinant plasmid vector comprising a DNA sequence which codes for a recombinant polypeptide corresponding to a polypeptide selected from the group consisting of FP3 [SEQ ID NO 22], FP4 [SEQ ID NO 8], FP5 [SEQ ID NO 10], FP6 [SEQ ID NO 14], FP7 [SEQ ID NO 12], FP8 [SEQ ID NO 16], FP9 [SEQ ID NO 18] and FP10 [SEQ ID NO 20].

2. (Withdrawn) The plasmid vector of claim 1, wherein the plasmid vector is selected from the group consisting of pGEX and pET plasmid vectors.

3. (Withdrawn) The plasmid vector of claim 2, wherein the plasmid vector is pET-32a.

4. (Withdrawn) The plasmid vector of claim 1, wherein the DNA sequence comprises one selected from the group consisting of SEQ ID NO 21, SEQ ID NO 7, SEQ ID NO 9, SEQ ID NO 13, SEQ ID NO 11, SEQ ID NO 15, SEQ ID NO 17, and SEQ ID NO 19.

4. (Withdrawn) An organism transfected with the plasmid vector of claim 1.

5. (Withdrawn) The organism of claim 4, wherein the organism is *Escherichia coli*.

6. (Previously Presented) A recombinant polypeptide comprising a sequence corresponding to one of FP3, FP4, FP6, FP7, FP8 and FP10.

7. (Previously Presented) A kit comprising:
a first recombinant polypeptide wherein the first recombinant polypeptide is the recombinant polypeptide of claim 6, and
a second recombinant polypeptide.

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8. (Previously Presented) The kit of claim 7, wherein the second polypeptide comprises a sequence corresponding to one selected from the group consisting of Ag15 [SEQ ID NO 2], FP3, FP4, FP5, FP6, FP7 FP8, FP9 and FP10, wherein the first recombinant polypeptide is different from the second recombinant polypeptide.

9. (Previously Presented) The kit of claim 7, wherein the first recombinant polypeptide is FP4 and the second recombinant polypeptide is FP6.

10. (Previously Presented) The kit of claim 7, further comprising a third recombinant polypeptide selected from the group consisting of Ag15, FP3, FP4, FP5, FP6, FP7 FP8, FP9 and FP10, wherein the first recombinant polypeptide, the second recombinant polypeptide and the third recombinant polypeptide are different.

11. (Previously Presented) The kit of claim 10, wherein the first recombinant polypeptide corresponds to FP4, the second recombinant polypeptide corresponds to FP6 and the third polypeptide corresponds to FP10.

12. (Withdrawn) A method of detecting the presence of anti-*Trypanosoma cruzi* antibodies in a sample from a subject, comprising:

(A) contacting the sample with a polypeptide comprising an amino acid sequence selected from the group consisting of FP3, FP4, FP6, FP7, FP8 and FP10 or an immunoreactive fragment thereof, and

(B) detecting a specific binding interaction with an antibody in said sample, wherein the binding interaction comprises a specific binding between antibody in the sample and an epitope contained within the amino acid sequence set forth in FP3, FP4, FP6, FP7, FP8 and FP10 and wherein said specific binding interaction indicates past or present infection with *Trypanosoma cruzi*.

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13. (Withdrawn) The method of claim 12, wherein the polypeptide of step A is immobilized on a carrier molecule or a solid phase.
14. (Withdrawn) The method of claim 12, wherein the polypeptide of step A has a sequence obtained from a strain or clone of *Trypanosoma cruzi*.
15. (Withdrawn) The method of claim 12, wherein the polypeptide has had one or more amino acids truncated.
16. (Withdrawn) The method of claim 12, wherein the step of detecting anti-*Trypanosoma cruzi* antibodies bound to the immobilized polypeptide is carried out by adding at least one compound that detects the antibodies.
17. (Withdrawn) The method of claim 16, wherein the at least one compound that enables detection of the anti-*Trypanosoma cruzi* antibodies is selected from the group consisting of a colorimetric agent, a fluorescent agent, a chemiluminescent agent and a radionucleotide.
18. (New) The kit of claim 7, wherein the first polypeptide is FP3.
19. (New) The kit of claim 7, wherein the first polypeptide is FP3, and the second polypeptide is FP6.
20. (New) The kit of claim 19, further comprising a third polypeptide, wherein the third polypeptide is FP10.